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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 886,144	06/20/2001	Jurgen Kleinschmidt	03528.0050.CNUS01	6869

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EXAMINER

WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/886,144

Applicant(s)

KLEINSCHMIDT ET AL.

Examiner

Ulrike Winkler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 10 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 10 March 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1 ☐ Certified copies of the priority documents have been received.
- 2 ☐ Certified copies of the priority documents have been received in Application No. _____.
- 3 ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

The Amendment filed March 10, 2003 (Paper No. 8) in response to the Office Action of September 10, 2002 is acknowledged and has been entered. Claims 1-9 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Specification

The Office acknowledges the receipt of the substitute specification.

Drawings

Formal drawings and photographs have been submitted which fail to comply with 37 CFR 1.84. Please see the form PTO-948. Correction is required.

Claim Rejections - 35 USC § 112

The rejection of claims 1, 2 and 8 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** the claims now refer to the antibody deposit number.

The rejection of claims 1, 2 and 5 contains the trademark/trade name "CNBr-activated sempharose®" and "NHS-activated sempharose®" **is withdrawn** in view of applicant's amendment to the claims.

The rejection of claims 1, 2 and 8 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention **is withdrawn** in view of the statement by an attorney of record over his or her signature and registration number showing that all restrictions upon availability to the public will be irrevocably removed upon granting of the patent.

Claim Rejections - 35 USC § 103

The rejection of claims 1-9 under 35 U.S.C. 103(a) as being unpatentable over Shimada et al. (WO96/29349) and Wistuba et al. (Journal of Virology, Sept. 1995) and further in view of Harlow (Antibodies, a laboratory manual, 1988) **is maintained** for reasons of record.

Applicant's arguments have been fully considered but fail to persuade. Applicant's argument is that the references do not teach an elution of 0.5 to 4.5 M $MgCl_2$. Harlow teaches the use of several matrixes for the use of affinity purification purposes, such as cyanogens bromide activated beads (page 532) the reference also teaches several methods of eluting the antigen from the bound antibody antigen complex (page 551), one of the gentlest methods is using $MgCl_2$, the concentration range suggested ranges from 3-5 M. The release of an antigen from an antigen-antibody complex occurs from 3-5 M $MgCl_2$.

MPEP 2144.05

In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990) (The prior art taught carbon monoxide concentrations of "about 1-5%" while the claim was limited to "more than 5%." The court held that "about 1-5%" allowed for concentrations slightly above 5% thus the ranges overlapped.);

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Applicants can rebut a *prima facie* case of obviousness based on overlapping ranges by showing the criticality of the claimed range. "The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims. . . . In such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 716.02 - § 716.02(g) for a discussion of criticality and unexpected results.

The Office maintains that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to utilize affinity purification methods as taught Shimada et al. for the purpose of purifying AAV and applying the antibody as taught by Wistuba et al. to purify AAV-2. One having ordinary skill in the art would have been motivated to do this in order to purify commercial level quantities of infectious virus AAV-2 suitable for therapeutic purposes. One having ordinary skill in the art would have reasonable expectation of success utilizing the antibody as taught by Wistuba et al. for the purpose of purification as taught by Shimada et al. because the antibody is directed to the CAP protein as were the antibodies by Shimada et al. AAV-2 is a parvovirus that affects humans and is the virus construct most often used in attempts to transfer genes of interest into human cell lines. It would have been obvious to one of ordinary skill in the art at the time the invention was made optimize the affinity chromatography conditions following the standard art known procedures (Harlow et al.), this includes the choice of solid support and the method of eluting the antigen which is directly dependent on the specific antibody used. Elution conditions must be custom tailored because each antibody will have a different affinity/avidity for the antigen and therefore the optimum conditions must be experimentally established. One having ordinary skill in the art would have been motivated to package the required components into a kit for the sake of conveniently

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providing the reagents to unskilled personnel. Therefore, the instant invention is obvious over Shimada et al. and Wistuba et al. and further in view of Harlow.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Ulrike Winkler, Ph.D.


JAMES HOUSEL 6/1/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600